Required documents/information for clinical trials, according to the Clinical Trials Ordinance, ClinO

Remarks:

The document list on the upload screen/s in BASEC will be generated automatically depending on your entries on screens 1-3.

In BASEC you will find links to templates and further information under each document category on the upload-screens. (All templates are also available on www.swissethics.ch/en/templates)

Some information necessary for clinical trials combined with **further use studies** is already asked in the application form.

Documents that have to be signed are the following: protocol (item 4), contract(s)/letter of delegation (item 9, 38), insurance (item 10), and staff list (item 13).

Other important documents not falling within these categories can be uploaded in the miscellaneous category "Varia".

If you have questions that are not answered in the document or in the FAQ section in BASEC, please contact the competent ethics committee or swissethics.

R = This document/information is required. In BASEC this is labelled with an asterisk < * >

A = Mandatory if applicable (for example a contract between an investigational site and the sponsor is mandatory while the document is not requested in an investigator-initiated trial with no external sponsor or any other external collaborator). In BASEC this is labelled with an asterisk in parentheses < (*) >.

		Clinical trials										
Document number in BASEC	**Study type:**	medicinal products and transplant products			In vitro diagnostic		gene therapy or pathogenic/genetically modified organisms			Trans-plantation		Other clinical trials
	Risk category	A	B	C	A	C	A	B	C	A	C	A & B
1	**Covering letter**	R	R	R	R	R	R	R	R	R	R	R
2	**Synopsis of the study plan** *A separate synopsis is not required. A synopsis is generally already included in the protocol.* *(Multicentre clinical trials in the language of the Lead EC or in English. Monocentric trials in the language of the EC.)* *Template (.docx) in DE, FR, IT, EN available at swissethics.ch*	A	A	A	A	A	A	A	A	A	A	A
3	**Participant information sheet and informed consent (ICF)** *Template for drafting information for participants (.docx) in DE, FR, IT available at swissethics.ch*	R	R	R	R	R	R	R	R	R	R	R
4	**Study plan (protocol), signed and dated** *Clinical Protocol Template (.docx) in EN available at swissethics.ch*	R	R	R	R	R	R	R	R	R	R	R
4a	**Monitoring plan** If the final version of the monitoring plan is not available at the moment of the submission, it is acceptable to submit a draft version or an outline of the monitoring strategy.	A	A	A	A	A	A	A	A	A	A	A
5	**CRF (Case Report Form)** *Draft acceptable provided the final document is available within the next 30 days (monocentric) or 45 days (multicentric).*	R	R	R	R	R	R	R	R	R	R	R
6	**Investigator's / Project Leader's CV**, dated	R	R	R	R	R	R	R	R	R	R	R
7	**Investigator's proof of GCP training**	R	R	R	R	R	R	R	R	R	R	R
8	**Details on infrastructure suitability and availability at the location where the trial is executed**	A	A	A	A	A	A	A	A	A	A	A
9	**Agreement between sponsor/commissioned institution / grant provider or other third parties and the investigator** *Regarding trial financing, the allocation of tasks, the investigator's compensation and the publication.* *Template (.docx) in EN available at swissethics.ch.* *Draft acceptable provided the final document is available before the inclusion of the first patient / participant.*	A	A	A	A	A	A	A	A	A	A	A

		Clinical trials										
Document number in BASEC	**Study type:**	medicinal products and transplant products			In vitro diagnostic		gene therapy or pathogenic/genetically modified organisms			Trans-plantation		Other clinical trials
	Risk category	A	B	C	A	C	A	B	C	A	C	A & B
10	**Insurance** *General Insurance Conditions (GIC) for clinical trials in Human Research (.pdf) in DE, FR, EN and* *Insurance (template) for clinical trials (.docx) in DE, FR, IT, EN available at swissethics.ch*	A	R	R	A	R	A	R	R	A	R	A / R
11	**Other documents handed over to study participants** *Such as advertisements used in recruitment, patient journals, questionnaires, scores, translations of study documents, recruitment letters etc.*	A	A	A	A	A	A	A	A	A	A	A
12	**Details on nature and scope/value of compensation for participants**	R	R	R	R	R	R	R	R	R	R	R
13	**Other personnel** *Template (.docx) in EN available at swissethics.ch*	A	A	A	A	A	A	A	A	A	A	A
14	**Information on secure handling of biological material and personal data, and in particular on the storage thereof** *According to art. 18 ClinO (in DE, FR, IT) and art. 5 ORH (in DE, FR, IT).*	R	R	R	R	R	R	R	R	R	R	R
15	**Information on reviews of this proposal by other Ethics Committees, or Regulatory Authorities (Foreign or Swiss)**	A	A	A	A	A	A	A	A	A	A	A
16	**Professional information as approved by Swissmedic** *Please copy relevant information from Swissmedic and upload here.*	R	R				R					
17	**Deviation from the prescribing information according to the study plan**		R					R				
18	**Proof of proper labelling of the therapeutic products and compliance with Good manufacturing Practice** *Please send us a description and/or a sample of your study specific label. The GMP part has only to be answered if non proprietary products are used e.g. repacked medicinal products.*	R					R	R				
19	**Investigator's Brochure (IB): Current clinical and non-clinical information on the product under investigation and its components**			R		R			R			

		Clinical trials										
Document number in BASEC	**Study type:**	medicinal products and transplant products			In vitro diagnostic		gene therapy or pathogenic/genetically modified organisms			Trans-plantation		Other clinical trials
	Risk category	A	B	C	A	C	A	B	C	A	C	A & B
20	**Conformity marking and deviation from intended use** *For clinical trials of in-vitro diagnostic bearing a conformity marking which is not used in accordance with the intended purpose or the instructions: Please provide the relevant documentation according to ClinO, Annex 4, Points 3.5 a. to f. (link in DE, FR, IT).*					R						
21	**Information on the conformity of in-vitro diagnostic (CE marking from a notified body)** *According to ClinO, Annex 3, point 1.8. (DE, FR, IT).*				R							
22	**Intended use of in-vitro diagnostic and instructions** *According to ClinO, Annex 3, point 1.8. (DE, FR, IT).*				R							
23	**Information about gene therapy as specified in Annex 4 chapter 4 of the Ordinance on Clinical Trials ClinO** *ClinO, Annex 4, Chapter 4. (DE, FR, IT).*						A	R	R			
24	**Details regarding the information and consent of the donor**									R	R	
25	**Proof of the origin & quality of the organs, tissues, or cells used** *In particular list all the tests, which have been performed in this connection.*									R		
26	**Proof of compliance with duties of care** *Particularly with regard to the assessment of fitness to donate and mandatory testing, and the procedure in the event of reactive text results.*									R		
27	**Authorisation** *Copy of the authorisation letter, if the handling of the organs, tissues or cells used is subject to authorisation under the Transplantation Act (link in DE, FR, IT).*									A		
28	**Transplantation using genetically modified human organs, tissues or cells** *Provide all further documents as listed in Annex 4, chapter 6.7 of the Ordinance on Clinical Trials ClinO (DE, FR, IT).*									R	R	

		Clinical trials										
Document number in BASEC	**Study type:**	medicinal products and transplant products			In vitro diagnostic		gene therapy or pathogenic/genetically modified organisms			Trans-plantation		Other clinical trials
	Risk category	A	B	C	A	C	A	B	C	A	C	A & B
34	**Table with values of estimated effective radiation dose** *The calculation of the effective dose must take into account all radiation sources used in the study and must include the uncertainty according to Art. 28 (DE, FR, IT) Radiological Protection Ordinance from 1994* *If you do not already have tables with values of the estimated effective radiation dose you can download the template of the table from screen 6, point 34 in BASEC.*	A	A	A	A	A	A	A	A	A	A	A
35	**Required authorisation for the use of ionising radiation according to article 28 of the radiological protection act** *See: Article 28 of the Radiological Protection Act of 22 March 1991 (link in DE, FR, IT).*	A	A	A	A	A	A	A	A	A	A	A
36	**Further documents as listed in Annex 2, chapter 3 of the HRO** *Provide all further documents as listed in Annex 2, chapter 3 of the Human Research Ordinance HRO (DE, FR, IT).*	A	A	A	A	A	A	A	A	A	A	A
37	**Further documents as listed in Annexe 3, chapter 5 of the ClinO** *Please provide all further documents as listed in Annexe 3, chapter 5 of the Ordinance on Clinical Trials ClinO (link in DE, FR, IT).*	A	A	A	A	A	A	A	A	A	A	A
38	**Sponsor's delegation letter, signed** *If the sponsor's representative or the CRO acts as applicant, a delegation letter of the sponsor is required. If this information is contained in a contract, please upload this document.*	A	A	A	A	A	A	A	A	A	A	A
39	**Miscellaneous / Varia** *Please only add documents that don't fall in one of the above categories.*	A	A	A	A	A	A	A	A	A	A	A
40	**Pharmaceutical Quality Dossier for non-IMP (Investigational Medicinal Product)** *A template for the Pharmaceutical Quality Dossier is available on the swissmedic Webpage (licensing / clinical trial application) or you can download the template here.*	A	A	A	A	A	A	A	A	A	A	A
41	**Final report** *Submit the final clinical trial report within a year after completion or discontinuation of the clinical trial, unless a longer period is specified in*	A	A	A	A	A	A	A	A	A	A	A

		Clinical trials										
Document number in BASEC	**Study type:**	medicinal products and transplant products			In vitro diagnostic		gene therapy or pathogenic/genetically modified organisms			Trans-plantation		Other clinical trials
	Risk category	A	B	C	A	C	A	B	C	A	C	A & B
	the protocol, according to Art 38 paragraph 3 ClinO (DE, FR, IT) and a Art 62.c ClinO (DE, FR, IT) for Other clinical trials											

Required documents/information for local sites in multicentric studies.

Document number in BASEC		clinical trials
1	**Covering letter**	optional
2	**Synopsis of the study plan in English or local language** *If the synopsis/information about the synopsis provided on the main upload screen (screen 6) is neither in English nor in the language of the EC responsible for this additional site, please upload a separate version.* *Template (.docx) in DE, FR, IT, EN available at swissethics.ch.*	A separate synopsis is not required for the submission of clinical trials (KlinV, OClin, OSRUm). A synopsis is generally already included in the protocol.
3	**Participant information sheet and informed consent (ICF)** *Template for drafting information for participants (.docx) in DE, FR, IT available at swissethics.ch*	adapted to the local site(s)
4	**Signed study plan or signature page of the study plan** *Signed study plan or signature page of the study plan or protocol, signed and dated by the local investigator. The signature page has to include the title, version and date of the study plan/protocol.* *Clinical Protocol Template for (.docx) in EN available at swissethics.ch*	signature page signed by local investigator
6	**Investigator's / Project Leader's CV**, dated	CV of the local principal investigator
7	**Local investigator's proof of GCP training**	of the local principal investigator
8	**Details on infrastructure suitability and availability at the location where the trial is executed**	optional
9	**Agreement between sponsor/commissioned institution and local investigator** *Draft acceptable provided the final document is available within the next 30 days (monocentric) or 45 days (multicentric).* *Document about trial financing, the allocation of tasks, the investigator's compensation and publication.* *Template (.docx) in EN available at swissethics.ch*	local document/s (upload of drafts is acceptable for the first submission)
10	**Insurance** *General Insurance Conditions (GIC) for clinical trials in Human Research (.pdf) in DE, FR, EN and* *Insurance (template) for clinical trials (.docx) in DE, FR, IT, EN available at swissethics.ch*	[required only for risk categories B & C]
11	**Other documents handed over to study participants** *Such as advertisements used in recruitment, patient journals, questionnaires, scores, translations of study documents, recruitment letters etc.*	local document/s (optional)
13	**Other Personnel** *Template (.docx) in EN available at swissethics.ch*	Staff list/s when other persons are involved
39	**Miscellaneous / Varia** *Please only add documents that don't fall in one of the above categories.*	other important documents

Document number in BASEC		clinical trials
32	**Application documents for research projects involving deceased persons** *Please provide all further documents as listed in Annex 2, chapter 6, of the Human Research Ordinance HRO. (Link in DE, FR, IT).*	-
33	**Application documents for research projects involving embryos and foetuses from induced abortions/spontaneous abortions including stillbirths** *Please provide all further documents as listed in Annexe 2, chapter 7, of the Human Research Ordinance HRO (link in DE, FR, IT).*	-
34	**Table with values of estimated effective radiation dose** *The calculation of the effective dose must take into account all radiation sources used in the study and must include the uncertainty according to Art. 28 (DE, FR, IT) Radiological Protection Ordinance from 1994* *If you do not already have tables with values of the estimated effective radiation dose you can download a template of the table here.*	local document/s (if radiation is involved)
35	**Required authorisation for the use of ionising radiation according to article 28 of the radiological protection act** *See: Article 28 of the Radiological Protection Act of 22 March 1991 (link in DE, FR, IT).*	local document/s (if radiological examinations are involved not using standard clinical equipment)

The numbers on the local screen don't necessarily correspond to the numbers in the main document screen

Combined clinical trials with further use of biological material and/or health-related personal data: please upload the consent document(s) in field no. 3. If you are unable to obtain a legal consent please upload in the field “Varia”: The designation of the biological material or health-related personal data of which further use is to be made, the designation of the group of persons who are to be entitled to pass on the biological material or the health-related personal data and the designation of the person who is to be entitled to receive the biological material or the health-related personal data.

Research involving ionising radiation in any form: Also provide the documents in field no. 34